



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|--------------------------------|------------------|
| 10/759,892 | 01/16/2004 | Mary Aldritt | 208-022US1 | 8476 |
| 27791 | 7590 | 02/19/2010 | | |
| ALLISON JOHNSON, P.A. LAKE CALHOUN EXECUTIVE CENTER 3033 EXCELSIOR BLVD., SUITE 467 MINNEAPOLIS, MN 55416 | | | EXAMINER HOFFMAN, SUSAN COE | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1655 | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 02/19/2010 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patent@ajiplaw.com
allison@ajiplaw.com

Office Action Summary

Application No.

10/759,892

Applicant(s)

ALDRITT ET AL.

Examiner

Susan Coe Hoffman

Art Unit

1655

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-16, 18 and 20-40 is/are pending in the application.
- 4a) Of the above claim(s) 20-30 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16, 35 and 37-40 is/are allowed.
- 6) ☒ Claim(s) 1, 3-15, 18 and 31-34 is/are rejected.
- 7) ☒ Claim(s) 36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The amendment filed October 9, 2009 has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
2. Claim 2 has been cancelled in this amendment.
3. Claims 35-40 have been added in this amendment.
4. Claims 1, 3-16, 18 and 20-40 are pending.
5. In the reply filed on July 11, 2006, applicant elected Group I, now claims 1-16, 18 and 31-40, without traverse.
6. Claim 20-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 11, 2006.
7. Claims 1-16, 18 and 31-40 are examined on the merits.

Claim Rejections - 35 USC § 103

8. Claims 1, 3-5, 8-10, 13, 15, 18, and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan (AU 200157788) in view of Lieberman et al. eds. (*Pharmaceutical Dosage Forms: Tablets*. Second Edition, volume 1. New York: Marcel Dekker, Inc. 1989. pp. 285-303) for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that Lieberman does not expressly teach how to formulate the claimed tablets. Applicant argues that Lieberman does not teach how to select an appropriate binder or how much binder to use. Applicant argues that Brennan also does

not teach which binder to use and how much to use to achieve a tablet that has the disintegration characteristics claimed by applicant in the claims. Applicant argues that the declaration of Kyle Johnson (filed March 13, 2009) shows that it was difficult to achieve a tablet taught by Brennan which did not display capping at a lower hardness. Applicant argues that Lieberman only provides general guidelines to achieve effervescent tablets and an artisan would have to perform a number of experiments to arrive at the tablet claimed by applicant. Applicant argues that Brennan does not teach the amounts of binder claimed by applicant and does not teach a tablet with the characteristics claimed by applicant.

However, these arguments are not persuasive. When formulating the tablet taught by Brennan, an artisan of ordinary skill would recognize that the tablet taught by Brennan has unwanted characteristics such as capping, filming, and slow dissolution. An artisan would reasonably look to Lieberman to correct these problems. Lieberman gives specific suggestions on how to correct these problems. As applicant points out, Lieberman teaches that the use of a binder and how much binder used has a direct effect on the lamination, capping, picking and disintegration of the tablet. Lieberman states that too much binder retards disintegration but too little binder leads to laminating, capping and picking. Lieberman also point to lactose as a binding substance (see pages 291 and 299). Brennan uses lactose in the effervescent tablet (see page 8). Thus, an artisan would recognize that lactose in the tablet of Brennan is a binding substance. The artisan would be motivated to modify the amount of lactose in Brennan's tablet to improve the disintegration characteristics of the tablet as suggested by Lieberman. This modification of the amount of lactose in the tablet of Brennan is not considered to be "obvious to try" but rather specifically suggested by Lieberman. Lieberman recognizes the problems

associated with the amount of binder and suggests varying the amount of binder used.

Lieberman specifically states that "Formulating must be individually tailored to achieve adequate binding and lubrication with minimal negative effects to the finished tablet (see page 299)."

"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Therefore, based on the specific suggestions by Lieberman, an artisan of ordinary skill would be motivated to modify the amount of the binder lactose used in the tablet taught by Brennan to achieve a tablet that has a quick disintegration time and does not exhibit picking, capping, and lamination.

Applicant argues that the references do not teach how to achieve a tablet with a hardness of at least 5 kilopond that disintegrates in the manner claimed. However, as discussed above, Lieberman teaches that modifications of the binding system result in improvements in the disintegration of the tablets. In addition, Lieberman teaches that the lubrication in the tablet also has a direct effect on the hardness of the tablet (see page 299). Thus, modification of the lubrication of the tablet would also result in modifications to the hardness of the tablet.

9. Claims 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan and Lieberman as applied to claims 1, 3-5, 8-10, 13, 15, 18, and 31-34 above, and further in view of Usukura (JP 2001-342142 - translation provided) for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that Usukura does not cure the deficiencies

of the combination of Brennan and Lieberman. However, as discussed above, the combination of Brennan and Lieberman is not considered to be deficient.

10. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan and Lieberman as applied to claims 1, 3-5, 8-10, 13, 15, 18, and 31-34 above, and further in view of Korab (US 4,704,269) for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that Korab does not cure the deficiencies of the combination of Brennan and Lieberman. However, as discussed above, the combination of Brennan and Lieberman is not considered to be deficient.

11. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan and Lieberman as applied to claims 1, 3-5, 8-10, 13, 15, 18, and 31-34 above, and further in view of Mann (US 2002/0102336) for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that Mann does not cure the deficiencies of the combination of Brennan and Lieberman. However, as discussed above, the combination of Brennan and Lieberman is not considered to be deficient.

Applicant also argues that Mann teaches using a cranberry fruit concentrate to inert solid in a ration of 15.7:1 rather than the 25:1 ratio taught by Brennan. Applicant argues that an artisan would not be motivated to employ a product that provides less cranberry fruit per gram of material than that provided by Brennan. However, this argument is not persuasive. The artisan would be motivated to use an amount of cranberry fruit concentrate to arrive at the dosages suggested by Brennan and would further be motivated to use an amount of magnesium hydroxide

to improve stability of the cranberry as suggested by Mann. The artisan would expect that the inclusion of the magnesium hydroxide would improve the product of Brennan because it would increase the stability of the product. Thus, the combination of Brennan, Lieberman and Mann is still considered to be valid.

Allowable Subject Matter

12. Claims 16, 35 and 37-40 are allowed.
13. Claim 36 is allowable over the prior art, but it is objected to because of the following informalities: the claim does not end in a period. Appropriate correction is required.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Coe Hoffman/
Primary Examiner, Art Unit 1655